CDC/IDSA Clinician Call

BD BACTEC Blood Culture Bottle Shortage

- Hosted in partnership with ASM, SHEA and PIDS

July 23, 2024

Q&A

This is the Q&A transcript from the Zoom webinar held on Jully 23, 2024. The views and opinions expressed here are those of the presenters and do not necessarily reflect the official policy or position of the CDC or IDSA. Involvement of CDC and IDSA should not be viewed as endorsement of any entity or individual involved.

1. **In the call last week with the CDC, we heard that BD is speaking with the FDA about potentially extending the expiration dates on some Bactec bottles (lots? SKUs?). Could we get an update on that discussion from BD and/or the FDA representatives?**

   Romney Humphries, PhD: We have received some expired lots of blood cultures with 1 month extensions.

   Attendee: BD sent out a notice to clients with specific lot #s to extend the expiration of select lots by an additional month. Reach out to your BD rep. to see if you have received those lots.

   Chris Beddard, BD: BD will be issuing a customer communication for US customers that received specific lots of 4 SKUs dated through the end of the calendar year which supports their use for one month beyond the printed date on the bottle. The specific product lots and detail will be in a letter that we will post to our microsite and will be available via their BD Account Representative.

   Carl Newman PhD: Recently BD updated the expiration dates on certain BACTEC bottles based on a review of available stability data by the manufacturer and it is FDA's understanding that they notified affected customers. FDA suggests that any questions about a particular SKU or lot be directed to BD and FDA will continue to discuss with BD with regards to the current situation.

2. **What about aerobic bottles? We are struggling to keep those on our shelves and only getting anaerobic allocated. Are folks using anaerobic only/pediatric bottles for adult populations?**

   Romney Humphries, PhD: We investigated this, but did not take this approach due to the strict aerobes we see in blood cultures. We are using them for clearance purposes (e.g., S,. aureus bacteremia) or using fungal bottles for Candida clearance.

   Attendee 1: We very rarely have any organisms grow in the anaerobic that don't aerobically unless true anaerobes. What about pediatric bottles, anyone try that?

   Romney Humphries, PhD: We often see organisms like Pseudomonas aeruginosa and Candida not growing in anaerobic bottles. The peds bottles (in our experience) are also in very short supply - we are receiving none currently.

   Attendee 2: We were told by BD (and also in IFU) that Pediatric bottles are not age based, rather volume based which could be used in both "pediatric" and "non-pediatric patients" that have limitations in the volume of blood collected.

Please note that the maximum volume of blood sample to be collected in BD Peds bottle is 5 ml from both pediatric and non-pediatric patients (adults).

3. **Will reverting to glass vials require validation to be performed?**

   Romney Humphries, PhD: per CLIA, yes - although you may consider taking a risk - based approach to this when determining the extent. For example, if you used glass bottles in the past, you may be able to do a very streamlined verification.

4. **Will FDA allow use of expired blood culture bottles?**

   Chris Beddard, BD: BD BACTEC™ Lytic Anaerobic media in glass (442265)

5. **Will the glass bottles have the same order # and be seamless for ordering?**

   Chris Beddard, BD: BD BACTEC™ Lytic Anaerobic media in glass (442265) is the correct Cat #. We are adding the SKU to all contracts and updating distributors.

6. **Is there any evidence that other manufacturers of blood culture bottles may be impacted by this shortage?**

   Carl Newman, FDA: At this time we are not aware of an issue with any other manufacturers. FDA is continuing to monitor the current situation and encourages laboratories and health care providers to notify us of shortages at your facilities by emailing deviceshortages@fda.hhs.gov

7. **How long will supply be limited?**

   Chris Beddard, BD: Based on actions currently deployed at our supplier and the temporary sourcing of glass bottles for BD BACTEC™ Lytic/10 Anaerobic/F Culture Vials, we expect to realize improvements in supply in September 2024. We continue to produce and allocate weekly with the current plastic vial supply.

8. **Is there any estimate for allocation reduction i.e. 10%, 50%, 75% etc.? What reduction in the current use rate will meet the supply available?**

   Romney Humphries, PhD: It depends on your distributor - our allocation has been <1% for aerobic bottles. Others are getting more.

9. **Why lytic ana instead of aerobic bottles?**

   Chris Beddard, BD: Based on our current manufacturing capabilities, we can most quickly launch the BD BACTEC™ Lytic Anaerobic media in glass (442265). Other media types require more specialized manufacturing processes which would take longer to deploy and given the urgent nature of the current supply situation we are looking to expedite product availability. By re-launching BD BACTEC™ Lytic Anaerobic media in glass (442265), we expect to improve overall quantities of all products including our BD BACTEC™ Plus Aerobic media (442023) and BD BACTEC™ Peds Plus media (442020).

10. **Should we expect that in September, there will be glass bottles for aerobic, anaerobic and pediatric bottles or only for anaerobic media?**

    Chris Beddard, BD: BD will have glass bottles for BD BACTEC™ Lytic Anaerobic media (442265) based on our manufacturing capability. We will continue to manufacture in plastic vials for all other media types.

11. **For BD: can you explain why plastics shortage seems to be impacting aerobic bottles more so than anaerobic bottles? Why glass only for anaerobic bottles? Is there an additional issue with the production of aerobic bottles?**

    Chris Beddard, BD: There is no challenge with the production of BD BACTEC blood culture vials by media type. We are incorporating other methods to produce / allocate by SKU to better meet regional demand changes.

12. **If supply is supposed to improve in September, why go down the road of glass bottles that will not be available until September? This implies the issue will last much longer than the September date we're being told**.

    Chris Beddard, BD: Based on actions currently deployed at our supplier to improve plastic vial supply and the temporary sourcing of glass bottles for BD BACTEC™ Lytic/10 Anaerobic/F Culture Vials, we expect to realize improvements in supply in September 2024.

13. **Is there a recommendation to collect a higher than normal blood volume to reduce need to recollect?**

    Romney Humphries, PhD: I believe it's best to maximize your draw within the FDA cleared indications of the bottles. 10 mL within each is best practice, for adults. Children, weight based. You really want to maximize the use of those few bottles available.

14. **This CDC presentation is NOT helpful. We are already doing all we can to collect blood cx properly. What we need to know is when appropriate to collect only one set of blood cx--e.g., f/u of S aureus bacteremia?**

    Valeria Fabre, MD: It will always be better to obtain 2 sets. Single sets have been implemented as last resource strategies.

15. **In terms of total volume of inappropriate blood cultures what department orders the most?**

    Aaron Milstone: Emergency department in our system has highest usage.

    Attendee 1: Similar here, but also had the greatest reduction when rationing was implemented, really helping us bring down use.

    Aaron Milstone: I should clarify that ED has the highest use.

    Attendee 2: That's what I assumed just based on patient volumes-- do either of you know what the breakdown is? Like % inappropriate from each?

    Attendee 1: Don't know what percent is inappropriate, though I can say that with hospital wide reductions of maybe 40% with rationing, we saw ED use drop about 60-70%. I think partnership with the ED, at least for our hospital, was key for us.

    Romney Humphries, PhD: Our adult ED in our academic hospital accounts for 30% of overall use of blood cultures across our 5 hospital system.

16. **90% of BC collected are negative. Were the repeat BC collected to document bacterial clearance included in the data?**

    Valeria Fabre, MD: Yes, that includes all. Except for the instances we outlined (S. aureus, S. lugdunensis, yeast and any organism causing endovascular infection) are negative in their vast majority.

17. **Is there any issue with resin bead availability for the aerobic Bactec bottles?**

    Chris Beddard, BD: There is no challenge with media or resin bead availability. The shortage is solely related to the plastic vial.

18. **As in the links from the July 10 FDA letter, 2 sets of cultures are recommended in this presentation. Is it acceptable to reduce to one set, even for patients with suspected severe sepsis?**

    Valeria Fabre, MD: Dr Humphries will discuss this. I also added a table for people to have as reference from a paper by Lee. Bottom line, you may miss 30% for pseudomonas and yeast, 20% for strep and enterobacterales.

19. **Has Hopkins built any CDS to support appropriate ordering?**

    Valeria Fabre, MD: We have made an electronic version of the algorithm and providers can access it when ordering BCx. We are now working to add a link to the most recent (last week) BCx and their results. In a collaborator institution, in ~50% of cases, clinicians decided not to order it! This is helpful for BCx for "persistent fever" "persistent leukocytosis"

20. **Where do you put CAP requiring hospitalization (i.e., severe) but where sputum is available?**

    Valeria Fabre, MD: It is likely that the CAP requiring hospitalization meet severe sepsis so will need BCx to not fail Sep-1. Data shows does not add much in terms of Dx....

21. **Usually, 2 set of blood cultures are approximately 10 minutes apart, with the shortage is there any changes in collection of blood cultures**

    Valeria Fabre, MD: We found limited evidence to wait any time in between sets. We have removed the waiting time from our BC collection policy. https://pubmed.ncbi.nlm.nih.gov/36310816/

22. **Apologies if this has been asked - have other centers moved away from follow-up blood cultures? I know Vanderbilt guidance suggested 1 set per 48 hrs. but am uncertain if this is all cultures or just those not needing follow-up (S. aureus bacteremia, for exp)**

    Romney Humphries, PhD: We are allowing follow up cultures for very limited indications (candida, s. aureus, etc.) and these must get microbiology director approval. We worked with ID on the indications where this is appropriate.

    Attendee: We are only doing f/u cultures for concern for endovascular infection, staph aureus/lugd, and candida, but are still doing two sets in those situations.

23. **Why would BCx Stewardship reduce CLABSI rate? Is that because of decrease in detection?**

    Aaron Milstone: In pediatrics, blood cultures are often drawn off central lines which have higher contamination rate, so reducing blood cultures leads to fewer contaminants which can meet definition of CLABSI.

    We know that many systems/hospitals have already stood up clinical guidelines to reduce cultures, based on Dr. Fabre's publications, but often with additional restrictions (e.g. only 1 BCx because of the shortage) or with ED- or sepsis-severity focused recommendations, or some other recommendations (e.g. when to do follow up blood cultures for Enterococcal bacteremia).

24. **Would IDSA or another body (AMS? SHEA?) be willing to create some kind of crowd sourced (potentially anonymous?) central repository of these guidelines? This would help us compare our approaches while avoiding the appearance of a formal clinical recommendation by the IDSA or the CDC.**

    Attendee 1: ASM Lab Practices Subcommittee is working on a document summarizing best practices during this shortage.

    Attendee 2: Good to know! Some level of survey information suggesting which practices are happening at what frequency would be helpful, given the different clinical support some practices might have and the different shortage severity some locations might be experiencing.

25. **What is your opinion on using blood diversion devices, therefore reducing contamination and the need to repeat BC?**

    Sarah Turbett, MD: I think diversion devices are helpful when contamination rates are high.

    Attendee: We implemented them at our facility. Contamination rate is <.4%

26. **If a patient is admitted with sepsis, can institutions ask that providers only perform 1 set of bottles or does CMS require 2 sets?**

    Romney Humphries, PhD: We checked on this, and it does not specify 2 sets. However, 2 sets is of course best practice.

27. **Many sites have gone to single sets. How do we reconcile the reduced sensitivity of a single set culture for the sake of saving bottles. Would this not be considered garbage in/garbage out? This says nothing about potential contaminants further muddying the waters.**

    Valeria Fabre, MD: Dr Humphries will discuss single BCx. We reduced overall use while increasing the number of BCx obtained as 2 sets. So, it really depends on your supply (how critical it is)

28. **Do you foresee a shortage on Pediatric bottles as well?**

    Carl Newman, FDA: BD previously issued a letter to customers identifying the products that may be impacted. https://www.medline.com/media/assets/pdf/vendor-list/June2024-BD-BACTEC-BloodCulture-MediaSupply.pdf

29. **Any cancer centers with heme/SCT-specific guidelines? Obviously many of the general guidelines apply but I am interested if anyone is using unique guidance for heme providers.**

    Romney Humphries, PhD: We are not using different guidance for this population, at this time.

    Attendee: We ended up implementing guidelines that are in common between all services to simplify things, though do include initial presentation of F+N as a reason for two sets,

30. **When you don't know what supplies you are going to get, how many you are going to get and when, how can you plan?**

    Romney Humphries, PhD: This has been our exact experience, and we acted quickly - and I am thankful we did, as it turns out we are getting very few to no bottles.

31. **I practice in Brazil - with no phlebotomist - only RN and MD are allowed to collect blood cultures, in any hospital at all - is there any study to show the importance (cost X effect.) of the phlebotomist?**

    Sarah Turbett, MD: There are studies that show the importance of trained phlebotomy in reducing contamination rates.

32. **Dr. Milstone---Can you remark on using ADULT blood culture bottles for PEDIATRIC patients? (such as for patients less than 5 kg?) How much volume can be inoculated into adult bottles but still have good sensitivity.**

    Attendee: https://academic.oup.com/ofid/article/2/suppl_1/1002/2635245

33. **How many months from the mfg. expiration date was the expired bottles that were used for the study done?**

    Sarah Turbett, MD: For the study I mentioned, it ranged from 4-7 months. For the bottles we looked at they were 100 days after their expiration.

34. **Can I vent anaerobic bottle?**

    Romney Humphries, PhD: We were told by BD you cannot as it limits the detection.

35. **Can one of the presenters comment on the restrictions applications in neutropenia and other immunocompromised patients (HCT)**

    Sarah Turbett, MD: We have not yet implemented any restrictions on the neutropenic population. We are analyzing the utility of repeat blood cultures in this population currently.

36. **What quality control measures might be appropriate when using expired bottles?**

    Attendee: This is the response I received from CAP when I asked about performing QC on expired bottles:

    I spoke with my manager and our micro team regarding the unavailability of BD blood culture media bottles. COM.30400 very clearly states that expired reagents cannot be used except in the case of rare blood bank reagents.

    I was told the CAP cannot approve the use of the expired media. It is up to your medical director to decide what to do in this situation. If he approves the option to use the expired lots following QC, be sure to carefully document why the expired media was used, what supports this decision and how the QC will be performed. Retain all records and correspondence. If your lab is cited during its next inspection, you would have to respond with this documentation and show a procedure that states it would not be done in other circumstances (added to your QC policy for example).

    You would also have to notify the ordering physicians of this event.
    Keep a list of the patients tested in this manner in case.

37. **Expired Media is not the solution. Agree w/ CAP. Facilities should have better inventory management in order to not have expired media- thus taking inventory from other users.**

    Sarah Turbett, MD: I agree that generally the use of expired media should not occur. But if it is the difference between an expired blood culture bottle or no blood culture bottle at all-and there is a QC framework-what is the best option? Food for thought as some placed have zero bottles.

38. **What verification / validation should labs do in order to use expired bottles, or is using data from one site acceptable?**

    Sarah Turbett, MD: I think it would be helpful for BD to release their stability data as I have to imagine they have some beyond the defined expiration dates. I also wonder if FDA could help define QC measures.

39. **Has anyone done Karius testing instead of blood cultures if there was concern for endovascular infection?**

    Sarah Turbett, MD: No, I do not feel this is an adequate replacement for blood cultures.

40. **What is your recommendation to hospitals/labs who are not BD customers (use BioMerieux)? Might be helpful to reinforce a standard message of stewardship. Pandemic taught us that supply stresses can spread in unexpected ways.**

    Sarah Turbett, MD: We have recommended that all facilities, including those not affected by the shortage to implement conservation strategies as likely only a matter of time before they are affected

    Attendee: Reference Lab with BioMerieux equipment are at capacity and cannot help with testing as well.

41. **Any recommendations for neutropenic fever? Use of biomarker to guide treatment duration?**

    Attendee: We advise against recurring cultures if the syndrome/vitals are unchanged and initial sets and maybe 48h f/u are neg. But ID guidance is best in those situations.

42. **In regard to Item # 442265 BD Bactec Anaerobic Media, we looked this item up and it looks like this item has been Discontinued from BD. Is this true?**

    Attendee: I agree with you. Looking at Fisher this is being mentioned as discontinued. My guess is due to allocation it will be by request through your sales representative.

43. **CDC recommends blood specimen diversion device. Could anyone speak about how to have the facility utilize these with the increased cost of each device.**

    Valeria Fabre, MD: We do not use diversion devices so cannot comment on this.

    Attendee 1: When you look at the overall ROI on reduction of false positives, savings on reduced bed stay, antibiotics, they pay for themselves. We had a huge return once implemented. We have about 80% compliance on all BCX collected.

    Attendee 2: We use diversion devices in ICU and waste tubes on gen med floors.

44. **If these stewardship/conservation methods are successful and followed prospectively, would you consider instituting as the "new norm"?**

    Sarah Turbett, MD: Yes.

    Attendee: I think getting rid of unnecessary surveillance and low indication cultures will hopefully stick.

45. **What group is heading blood culture conservation efforts at your respective hospitals? Antimicrobial stewardship? Infection control? Or someone else?**

    Valeria Fabre, MD: At Hopkins it is ASP, Infection control, Micro, and supplies.

    Attendee 1: Lab started, local ID, ED and IP leaders began initial mitigation steps while we engaged system leadership in ED, IP, IP, AMS pharmacy and Nursing.

    Attendee 2: ASP leading, with assistance from micro lab, infection control, and materials management.

46. **Possibly a silly question - but when you all do 2 sets for s.aureus bacteremia - do you mean 2 sets, or 1 set on different days (skip phenomenon) - my apologies if I'm misunderstanding.**

    Valeria Fabre, MD: I'd recommend 2 sets (not one set on different days)

47. **What exactly is the issue with the bottle manufacturing? Resin? line down? equipment? materials?**

    Carl Newman, FDA: The issue is related to manufacturing, not the availability of materials.

    Attendee: Plastic issues.

48. **Are BD blood culture bottles manufactured domestically or abroad? sorry I missed where the supplier is located.**

    Carl Newman, FDA: They are produced domestically.

49. **Any thoughts on T2 Biosystems Sepsis Panels as an alternative?**

    Romney Humphries, PhD: This detects a very limited number of pathogens (5 bacteria), so I would be hesitant to do that way.

50. **Can a EAU be issued from the FDA/CDC permitting use beyond expiration date?**

    Ryan Lubert, FDA: We will continue to monitor the situation and inform the public if significant new or additional information becomes available.

51. **With QC on using expired bottles, what frequency and monitoring would be useful? Eg weekly bottles spiked with staph aureus and E. coli? If it fails, what action is recommended - given no/limited alternatives and blood culture may already have been collected into expired bottles?**

    Sarah Turbett, MD: I think this is something we could ask FDA to weigh in on, especially in the setting of the shortage. Streamlined QC would be ideal but need to ensure safe practices.

52. **Could be useful to have stakeholders from CAP, CLIA on this call to address some questions about validations/verifications from the community during this BD BCx shortage crisis**

    Sarah Turbett, MD: Agree!

53. Where does CMS state 2 sets of blood cultures are required for sepsis bundle?

Attendee 1: CMS requires one set.

Attendee 2: As far as I know, it doesn't.

54. If there is a plastic issue with the bottle, could the rest of the BD products be applied to this as well? Blood collection tubes, transfer devices ect. as well?

Attendee: There is now another shortage on BD butterflies; not sure if its related or not.

55. Is it possible for FDA to implement stricker guidelines when to order blood culture since this is a national/worldwide issue?

Attendee: I am not sure. This doesn't affect any other manufacturer other than BD. Perhaps one aspect of diversification is to ensure that we don't buy products from a single company.

Q&A Answered Post Call

56.

57. If we go from plastic to glass bottles, we will need to validate I am assuming so not sure how this can help? But I guess something is better than nothing?

Sarah Turbett, MD: Yes, if glass bottles become available, clinical laboratories would need to perform a verification of them (assuming the FDA has cleared them for use). The extent of verification would need to be determined by clinical laboratories.

58. Is anyone aware of if CMS is considering modifications to the sepsis measure specifications due to recent supply chain issues affecting blood culture bottles? The current SEP-1 measure mandates a bundle of care including blood cultures, which has been challenging for our hospitals due to these supply issues. Would CMS consider relaxing some of the current requirements around blood culture collection during this supply crisis?

Sarah Turbett, MD: My understanding is that the measures do not stipulate 2 sets, so if people are restricting based on the set number, you may be ok to proceed.

59. Does CDC or IDSA endorse the practice of obtaining a single set of blood cultures during the initial evaluation of a patient with suspected severe sepsis, given the shortage?

Romney Humphries, PhD: This is a decision that needs to be made by each individual institution, based on their own practices and patient populations. Use of one set only does come with reduced sensitivity for bacteremia. This is one tactic, but other measures may be a better approach, depending on the context.

60. Or only one set f/u bld cx for persistently febrile patients with chronic necrotizing pancreatitis or neutropenia?

Sarah Turbett, MD: I think this all depends on the clinical scenario. If clinically stable/no change and only febrile, it might be reasonable to do this. I do believe NCCN guidelines have recommendations on repeat cultures in patients with F+N.

61. **When looking at our supplies, aerobic bottles are definitely limited- anaerobic bottles we have a better supply of. Best practice is to have the aerobic anaerobic bottle. If I only have anaerobic bottles and limited pedi bottles- what combination would be next best to draw?**

    This may depend on the patient risk factors. For example, patients on TPN where Candidemia is a risk, it would not be desirable to collect anaerobic bottles only. Similarly, patients at risk for organisms like Pseudomonas aeruginosa should obtain an aerobic culture. Patients with intra-abdominal infections may be ok to draw two anaerobic bottles. At our institution (VUMC) we are recommending, on a case-by-case basis for repeat cultures use of anaerobic bottles alone (e.g., S. aureus bacteremia clearance).

62. **Is anyone telling patients about this? If so, how are you doing this? Especially if you are entering crisis mode, where you are restricting use in ways that you anticipate could lead to some otherwise-avoidable adverse outcomes?**

    This is starting to be covered by major news outlets.

63. **Are there blood culture bottles available that can be read manually?**

    Blood cultures could be read manually by looking for turbidity, but this is hard to do in a commercial bottle.

64. **This is the response I received from CAP when I asked about performing QC on expired bottles: I spoke with my manager and our micro team regarding the unavailability of BD blood culture media bottles. COM.30400 very clearly states that expired reagents cannot be used except in the case of rare blood bank reagents. I was told the CAP cannot approve the use of the expired media. It is up to your medical director to decide what to do in this situation. If he approves the option to use the expired lots following QC, be sure to carefully document why the expired media was used, what supports this decision and how the QC will be performed. Retain all records and correspondence. If your lab is cited during its next inspection, you would have to respond with this documentation and show a procedure that states it would not be done in other circumstances (added to your QC policy for example). You would also have to notify the ordering physicians of this event. Keep a list of the patients tested in this manner in case.**

    As a laboratory director, I would develop a non-conforming event plan for this. I would perform QC on the expired bottles and document the relative risk of using expired bottles vs. no bottles. I would engage my risk department for their input. I think the key thing is to document.

65. **When considering patient populations to draw blood cultures on- our highest collection is from patients presenting in the emergency room. Would this be the most appropriate population to collect from? (Patient meets diagnostic criteria for blood culture BPA)**

    Sarah Turbett, MD: Data support stratifying when to draw blood cultures based on clinical syndrome/indication so I think this strategy is a reasonable place to start. For example, I think a patient with a UTI (either in the ED or inpatient setting) likely does not need blood cultures. I would refer to Dr. Fabre's presentation on low yield conditions for blood cultures.

66. **Can I use pediatric aerobic bottle to culture blood for adult patients?**

    This is probably suboptimal but can be done. In my opinion (RH) it's better than no blood culture.

67. **Are there mitigation plans for ID clinical trial protocols? Curious to know if the blood culture requirement for anti-infective trials will follow the some kind of algorithm presented in the earlier slide.**

    This is a great question; unfortunately, I do not have an answer.

68. **Is anyone drawing Aerobic bottles only for suspected infections that are above the diaphragm?**

    I believe the main shortage at this time is aerobic bottles.

69. **If only 1 bottle is drawn for order, can the bottle be a Lytic bottle - if so, should it be vented?**

    My understanding from the vendor (BD) is that venting the bottle is associated with significant risk of a false-negative result due to the instrument not reading the growth signals appropriately. As such, we have not gone this route.

70. **Do we have enough data for determining the clinical and statistical significance of Single Blood Cx bottle results. While I understand following updated Blood Cx algorithm guidelines will limit contamination events, how do you address ruling in/out the possible contaminants (S. epi. and other CONS) based results from a single Blood Cx draw.**

    It is really hard to rule out contaminants with one set. we have been dealing with this on a case-by-case basis. We are also spending substantial time educating on how important aseptic techniques with phlebotomy.

71. **one topic not addressed is high utilization of blood culture by ED. most ed has practice where nurses collect blood culture and hold it. just stopping this practice helped reduce ED utilization by 30-50%. we also created a Blood culture algorithm for ED and used a modified version of the Hopkins algorithm for med surge and ICUs**

    We also stopped the "rainbow draw" in the ED.

72. **How will testing for lactate and procal help in determining when to do a blood culture?**

    I think it is an interesting question. This is not something we have considered at our hospital but might be worth considering!

73. **Maybe I missed this, but what seems most relevant is how many patients are positive only on the *second* set, not how many were positive on just one set or the other. My hunch is that quite a few folks with a single set positive were positive on set 1, but negativ on set 2 (sometimes after Abx were started).**

    We chose to not analyze the data in this way as we were uncertain on how good the documentation was on which bottle the draw went in to, since the labels are printed and then the blood is drawn. For what it's worth, the split was 50-50.

74. **Manual blood cultures is not a solution for large institutions!**

    Indeed.

75. **How does this affect blood bank activities? Are there opportunities for stewardship there?**

    This is a great question; unfortunately, I do not have an answer.

76. When bringing down to collecting just one set, how can contamination be ruled in/out?

We are managing these on case-by-case basis, allowing repeat draws in selected cases.

77. Rather than hospitals using expired bottles, can BD revisit their expiry date and relabel even on a per lot basis? Surely, they must have done studies to give a better idea. Knowing that the bottles are not going to expire in 1 month but can be used along with reducing repeat sets could greatly extend the duration that we can use our current stock.

Agree!

78. How is this shortage impacting clinical trials requiring BC? Are they on hold?

This is a great question; unfortunately, I do not have an answer.

79. I have an example of a single set missing MSSA repeat positive on my list right now and that for me is the difference between a TEE and not a TEE, can we focus on evidence of single follow up culture?

This is a risk

80. Would that be related to the improvement of new technologies: T2/ Karious/ PCR?

These are relatively limited in their performance, and at this time they do not replace blood cultures

81. Can multiplex PCRs be used to triage who gets blood cultures?

These are relatively limited in their performance, and at this time they do not replace blood cultures

82. What comments have been used / are suggested to include on reports of expired blood culture bottle is used?

I think this likely needs to be tailored to the hospital but could consider adding something about the expired bottle passing internal QC despite the expiration (would suggest performing QC if hospitals are going to use expired bottles)

83. Can we use just an anerobic bottle for culture? Perhaps subculture aerobically after 12 hours of incubation. What would we miss?

The risk would be strict aerobes - like Candida, Pseudomoans aeruginosa etc. These sometimes grow in the anaerobic bottle, but it is not a given.

84. Any suggestion of processing if we have no bottles?

There are still some manual BCB systems available-might be worth seeing if you can get those?

85. Is this experience one that emphasizes the need to be in a constant mode or rational utilization?

I think this situation, while extreme, is a good opportunity to return to best practices and implement evidence based stewardship algorithms.

86. What is the predicted effect of this shortage on the demand for comparable product from other manufacturers? Is there an expected drain on these resources?

This is a great question. I know some institutions have purchased alternative systems in the setting of the shortage.

Carl Newman, PhD: At this time we are not aware of an issue with any other manufacturers. FDA is continuing to monitor the current situation and encourages laboratories and health care providers to notify us of shortages at your facilities by emailing deviceshortages@fda.hhs.gov

87. Wouldn't the use of expired bottles be very limited because they will be used up fast, and we will only be receiving new bottles on allocation?

Yes, although there are often pockets of expired bottles in institutions.

88. Can you share QC protocols to determine if bottles are ok, similar to COVID verification of emergency use assays?

Carl Newman PhD: Questions related to laboratory practice are typically outside of FDA's purview; however, FDA continues to monitor the current situation and will continue to keep health care providers and the public informed if new or additional information becomes available.

89. Where is the letter from the FDA extending the use of expired BC bottles?

Carl Newman PhD: FDA has not issued any letter extending expiration dates. We suggest that you contact BD with regards to any extended expiration dates.

The Following questions are or will be added to the FAQ on https://bdbactec-update.com/

- **What about the aerobic bottles?**
- **Shortage, do we expect supplies to tighten between now and the next update in two months? Will allocations be reduced further than they already have been?**
- **Can glass bottles be used for aerobic blood culture bottles? Anaerobic organisms are such a low number of the organisms we identify in positive blood cultures.**
- **Please confirm that there is a shortage for Platelet anaerobic/F and aerobic/F culture vials.**
- **Would the glass blood culture bottles be available to Australia consumer as well?**
- **Is it plastic ana lytic mpn 442021 being replaced with the ana lytic glass mpn 442265?**
- **Will Myco F/Lytic bottles be available in glass in US?**
- **Will our BD representatives send us these links to share with our hospital administrators and physicians?** Yes, and will be added to bdbactec-update.com
- **BD provided a letter extending the expiration date on specific lots of bottles. Can we expect further extensions on these lots to extend the life of our current inventory? What about future lots? Will they automatically have a longer shelf-life? –** Yes, and will be added to bdbactec-update.com
- **Do we have any estimate of how long this shortage will last?**

- **When looking at our supplies, aerobic bottles are definitely limited- anaerobic bottles we have a better supply of.**
- **Is anyone drawing Aerobic bottles only for suspected infections that are above the diaphragm?**
- **Rather than hospitals using expired bottles, can BD revisit their expiry date and relabel even on a per lot basis? Surely, they must have done studies to give a better idea. Knowing that the bottles are not going to expire in 1 month but can be used along with reducing repeat sets could greatly extend the duration that we can use our current stock.**
- **How long will the shortage go on?**
- **BD, will you be releasing info about extended expirations?**
- **We've started hearing rumors that the shortage may extend past September, can BD comment on the likelihood of that?**
- **What comments have been used / are suggested to include on reports of expired blood culture bottle is used?**
- **BD - Very unsatisfactory answer. And you knew you would be on this call and didn't think to ask about the stability data.**
- **Where is the letter from the FDA extending the use of expired BC bottles**
- **Is BD planning to produce aerobic and pediatric bottles with glass if this continues?**
- **Why is this affecting aerobic bottles more than anaerobic bottles?**
- **BD, do you all have a validation protocol? Also, will you all provide bottles for validations?**
- **Agree how do we not have clear and concrete data from BD on expected allocation?**
- **Is the shortage effecting the aerobic bottle, anaerobic bottle or both?**
- **will glass mycolytic bottles be available in US?**
- **Is anyone aware of if CMS is considering modifications to the sepsis measure specifications due to recent supply chain issues affecting blood culture bottles? The current SEP-1 measure mandates a bundle of care including blood cultures, which has been challenging for our hospitals due to these supply issues. Would CMS consider relaxing some of the current requirements around blood culture collection during this supply crisis?**
- **Will the problem be gone in September?**
- **Glass bottles require a verification and also a software update of your Bactec instrument**